SEP - 8 2004

K041617

PREMARKET NOTIFICATION 510(K) SUMMARY

STALIF TT™ SYSTEM

Company:

Surgicraft
16 The Oaks, Clews Road
Redditch, Worcestershire
United Kingdom
B98 7ST

Contact: Steve Trotman

Proposed Proprietary Trade Name: STALIF™ TT

Classification Name: 888.3060 Orthopedics

FDA Product Code Classification: MQP

Device Description: The Surgicraft STALIF™ TT is a radiolucent vertebral body replacement device used in conjunction with cancellous bone screws and is designed to restore biomechanical integrity from thoracic (T9 to T12) and lumbar spine (L1 to L5) following vertebrectomy or corpectomy for patients with spine tumors or trauma/ fracture. The system provides anterior column support both immediately after surgery and for prolonged periods in the absence of bone fusion.

Material: PEEK-OPTIMA LT1

Intended Use:

The STALIF™ TT device is indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the thoracolumbar spine (from T9 to L5).

The STALIF™ TT device is intended for use with supplemental internal fixation.

The supplemental internal fixation systems that may be used with the STALIF™ TT device, include but are not limited to, DePuy AcroMed titanium plate or rod systems (e.g., Kaneda SR, University Plate, M2, Isola, VSP, Moss Miami, TiMx, Monarch and Profile).

Predicate Device: DePuy AcroMed Stackable Cage™ System
K990148, K001340, K013382

Performance Data: Performance data were submitted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2004

Surgicraft Ltd.
c/o Ms. Janet M. Webb
Medvantage Inc.
121 W. Chestnut Street, #3506
Chicago, IL 60610

Re: K041617
Trade/Device Name: STALIF TT
Regulation Number: 21 CFR 888.3060
Regulation Name: Vertebral body replacement device
Regulatory Class: Class II
Product Code: MQP
Dated: June 2, 2004
Received: June 15, 2004

Dear Ms. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K041617
Device Name: STALIF TT
Indications for Use:

The STALIF™ TT device is indicated for the replacement, partial vertebrectomy and / or augmentation of a vertebral body due to destruction by tumor or fracture leading to the restoration of planar alignment, restoration of the height of the collapsed vertebral body and indirectly facilitating neural decompression. The device is intended for use as a vertebral body replacement in the thoracolumbar spine (from T9 to L5).

The STALIF™ TT device is intended for use with supplemental internal fixation.

The supplemental internal fixation systems that may be used with the STALIF TT device, include but are not limited to, DePuy AcroMed titanium plate or rod systems (e.g., Kaneda SR, University Plate, M2, Isola, VSP, Moss Miami, TiMx, Monarch and Profile).

Prescription Use ____X____ or Over-The-Counter Use _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041617